

CelloPure⁺ Phenyl

Hydrophobic Chromatography Media

Technical Datasheet

Aggregates removal

CelloPure⁺ Phenyl resin is a chromatography media, can remove aggregates efficiently from antibodies, synthesized by standard polysaccharide ligand modification technology. After affinity chromatography like protein A, protein L or protein G, the antibody samples are passed through CelloPure⁺ Phenyl chromatography, the aggregates are bound to the hydrophobic ligand of the chromatography media and antibody monomers are coming out in flowthrough fraction. CelloPure⁺ Phenyl can be used as flow-through purification mode that selectively binds such as aggregates or polymers.

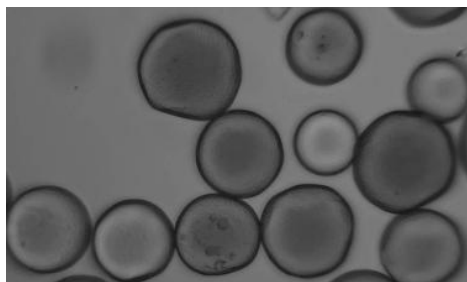
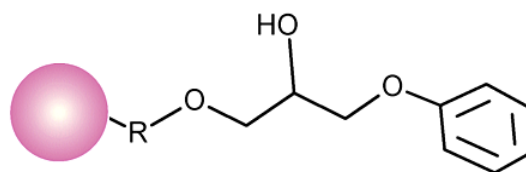


Fig 1. OPM analysis of CelloPure⁺ Phenyl resin

CelloPure⁺ Phenyl base resin

Crosslinked spherical Cellulose beads are prepared by unique process from crystalline natural polysaccharides, differing the physical characteristics from non-crystalline polysaccharides such as agarose. Thus, Biotrap resins are highly porous in nature (Fig. 1). Due to that porous nature of the highly crosslinked spherical cellulose bead, resins have unique mechanical strength.



Partial structure of CelloPure⁺ Phenyl

Ligand structure for CelloPure⁺ Phenyl media is described.

Characteristics of CelloPure⁺ Phenyl

The basic characteristics of CelloPure⁺ Phenyl resin are shown in table 1. CelloPure⁺ Phenyl resin is based on 90 µm (average) highly cross-linked cellulose beads. CelloPure⁺ Phenyl resin is designed for use in bio-pharmaceuticals

manufacturing processes. multiple types of hydrophobic chromatography resins we are making.

Characteristics		
Ligand	Phenyl group	
Type	Hydrophobic	
Base Matrix	Highly Cross-linked Dextran scaffold Cellulose Beads	
Particle Size (µm)	40 µm to 130 µm (Avg: 90µm)	
pH Working Range	2 to 14	
Operating Pressure	Up to 2 bar (0.2 Mpa)	
Chemical Stability	0.5N NaOH	
Binding Capacity (mg/mL resin)	HSA*	60
	Human-IgG**	20
Supplied	Suspension in 20% Ethanol	

*Buffer A: 20mM sodium phosphate, 2M Ammonium sulfate: pH: 7.2

Buffer B: 20mM sodium phosphate, 0.1M Sodium chloride, pH: 6.8

**Buffer A: 20mM sodium phosphate, 1M Ammonium sulfate: pH: 7.2

Buffer B: 20mM sodium phosphate, 0.1M Sodium chloride, pH: 6.8

Pressure-flow Properties of CelloPure+ Phenyl

CelloPure+ Phenyl enable high-flow operations, for efficient purification in biopharmaceutical industries high flow operation is essential. The figures below show pressure-flow velocity curves of CelloPure+ Phenyl (Fig. 3). CelloPure+ Phenyl is operable at practical flow velocities and pressures.

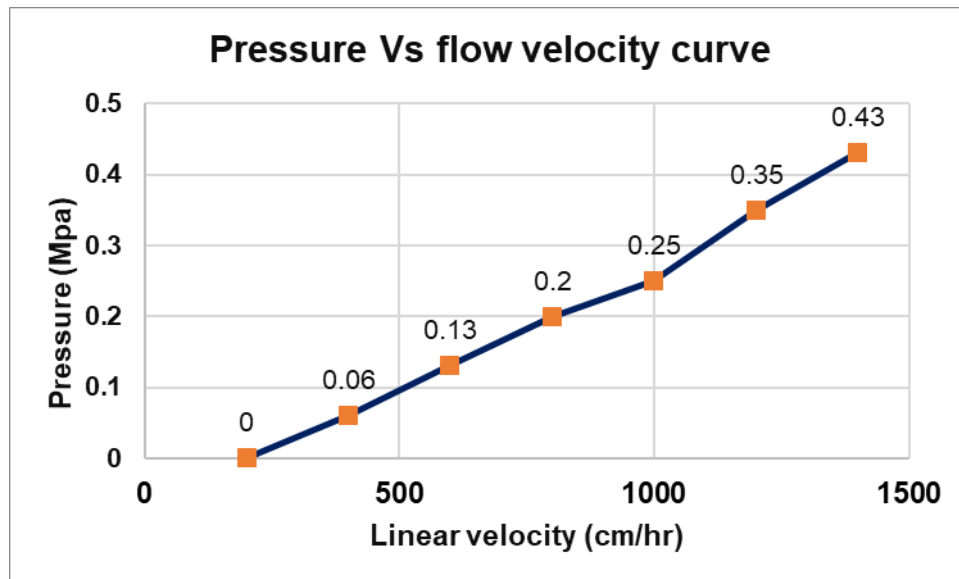
Fig.3 Pressure-flow property of CelloPure+ Phenyl

Column: I.D.2.6 cm x H 19.3cm

Mobile phase: Pure water, 23 - 25 °C

Resin was packed with a compression factor 1.35. S

ystem pressure was excluded from the data.



Purification of antibody aggregates

CelloPure+ Phenyl is the best chromatography resin for removing aggregates from monoclonal antibodies in flow-through mode. Antibody aggregates were removed using the monoclonal antibody purified with a protein A or protein L columns, CelloPure+ Phenyl can be worked with low electrical conductivity and has high agglomerate removal properties. In this study, the conductivity of the sample was adjusted to 14 mS / cm.

Column: 1 mL Mini-Column Flow rate: Residence time 4 min (75 cm/h)

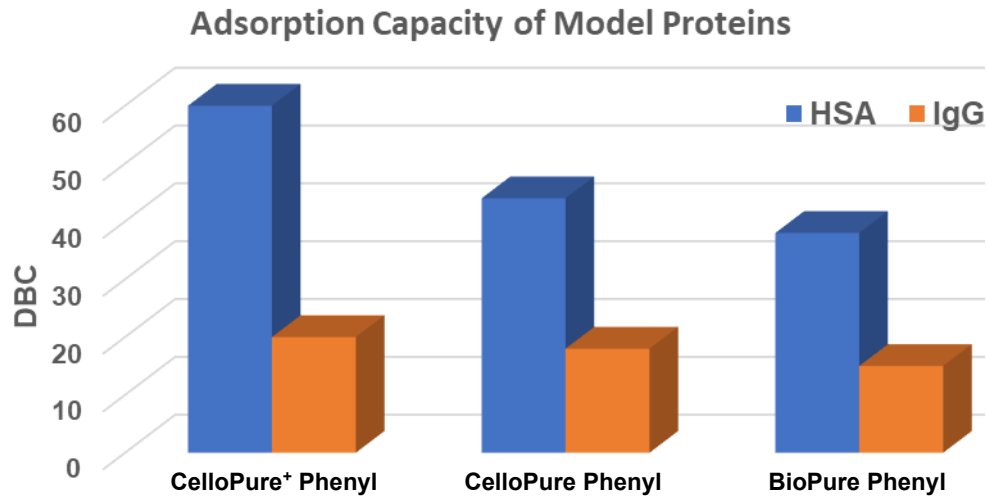
Sample: Purified mAb with Protein A resin 6.6 mg/mL,

pH6, 14 mS/cm

Antibody load: 93 mg mAb/ mL_cv

Equilibration/ wash : 20 mM AcOH-Tris + NaCl, pH6,

Resin	Aggregate % (Before load)	Aggregate % (After load)	Recovery [%]
CelloPure+ Phenyl	2.8	0.03	89



For HSA Buffer A: 20mM sodium phosphate, 2M Ammonium sulfate: pH: 7.2

Buffer B: 20mM sodium phosphate, 0.1M Sodium chloride, pH: 6.8

For IgG Buffer A: 20mM sodium phosphate, 1M Ammonium sulfate: pH: 7.2

Buffer B: 20mM sodium phosphate, 0.1M Sodium chloride, pH: 6.8

Dynamic Binding Capacities of CelloPure+ Phenyl

CelloPure+ Phenyl have high efficiency in mass transfer and excellent Dynamic Binding Capacities, particularly for large biomolecules like Immunoglobulins (IgG) also for HSA (Human Normal Albumin) and Ribonuclease. Because of these special qualities, BioTrap CM media can be used in downstream processes in the purification of biopharmaceuticals.

Repeat use CelloPure+ Phenyl can be used repeatedly.

For cleaning-in-place, use a cleaning solution containing 0.5 M sodium hydroxide and 30% isopropanol. By performing cleaning-in-place with an appropriate cleaning solution, the adsorption performance did not change even after repeated use 60 times.